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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,505	11/28/2001	Raymond J. Wong	3192-002	2941

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EXAMINER

MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,505

Applicant(s)

WONG, RAYMOND J.

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 40-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 50-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 40-49, drawn to a method to regenerate spent dialysis fluid, classified in class 210, subclass 644+.
- II. Claims 50-56, drawn to an apparatus for conducting dialysis comprising a sorbent cartridge, classified in class 210, subclass 321.71.

The inventions are distinct, each from the other because of the following reasons:

Claims 1-39 and 57-59 link inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1-39 and 57-59. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed

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can be practiced by another materially different apparatus which does not use a sorbent cartridge, such as a single pass dialysis machine which uses a water source and a water purification system.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Luke Kilyk on May 23, 2002 a provisional election was made with traverse to prosecute the invention of Group II, claims 50-56 and linking claims 1-39 and 57-59. Affirmation of this election must be made by applicant in replying to this Office action. Claims 40-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

Claim 39 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 38. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "zirconium phosphate". There is insufficient antecedent basis for this limitation in the claim. Claim 16 depends from claim 15, which in turn depends from claim 14 and from claim 1. For examination purpose, the examiner considers claim 16 as positively reciting zirconium phosphate layer. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,11,12,19, 21,29,30 and 50-57 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Polak et al (US 4,650,587).

Polak teaches a sorbent cartridge comprising at least sodium zirconium carbonate (see col 5 line 68 – col 6 line 11) as in claims 1 and 11. It is present as a layer as in claims 2 and 12 (fig 2 shows the absorbent as a layer; note col 6 lines 9-11). The composition of sodium zirconium carbonate is as given in col 6 lines 1-9 as in claim 19, except for the LOD of 30-40%, which is due to water loss. However, water loss from drying sodium zirconium carbonate is an inherent material property. The

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sodium zirconium carbonate would satisfy the properties listed in claim 21, being the same material. Polak also teaches an apparatus for conducting dialysis wherein the sorbent cartridge is in fluid communication with a dialyzer as in claim 50; the dialysis fluid could be spent hemo-dialysis fluid as in claim 51; the spent fluid could be restored to the original Na⁺ and HCO₃⁻ content as in claims 52, 54 and 57; and the apparatus could be in blood communication with a patient as in claim 53; peritoneal dialysis as in claim 55 and 56; (See fig, col 5 lines 60-68, and the fig, col 2 lines 25-40 and claim 8 of the incorporated ref). Re claims 29 and 30, the quantity of the sodium zirconium carbonate is a design/ optimization issue. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 20,38,39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polak '587.

Polak teaches the limitation of claim 1, but does not specify if the sodium zirconium carbonate satisfies the ANSI/AAMI standard. However, it would be obvious to one of ordinary skill in the art at the time of invention that the material being the same, it would satisfy such a requirement.

Claims 38 and 39 have the added limitation of two or more layers of the absorbents in the cartridge. Polak does not teach how the absorbents are structured in the cartridge. However, it would be obvious to one of ordinary skill in the art at the time of invention to have the absorbents in separately layered structure in the cartridge as a means for structuring the cartridge.

2. Claims 3-9,13-16,22-25,31-37,and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of Applicant's own disclosure of prior art.

Polak teaches all the elements of claims 1,11 and 50. Applicant's disclosure of the REDY (REDY) cartridge teaches the added limitations of the instant claims in specification pages 5-8 and figure 1 and 8 as follows:

Claim 3 and 13 add the further limitation of ZrP/group IVB metal phosphate, and claims 4 and 13 have ZrP as a layer as taught by REDY. Claim 5 adds the molecular composition of ZrP, and claim 6 adds the characteristics of ZrP (material property). Claims 7 and 8 add limits on residual sulfate and chloride in ZrP (material property). Claim 9, pH of ZrP is a material property. Claim 13 adds group metal phosphates (ZRP in REDY). Claim 14 and adds alumina, alumina supported urease, granular activated carbon, or combination thereof, with claim 15 adding these in layers

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(taught by REDY). Claim 16 adds the order of the layers as taught by REDY except for the position of the granular activated carbon layer (applicant admits that it could be in any order on page 21 lines 22-23). Claims 22 adds ZrO and 23 has ZrO in acetate form (taught by REDY). Claims 30 and 31 add limitations of quantities of ZrP [design/optimization: In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).]. Claim 32 and 36 add immobilized enzyme (Urease in alumina), ion exchange materials (sodium zirconium phosphate), and adsorbent for creatinine (activated carbon), etc, all taught by REDY. Claim 33 and 37 add chlorine removal material (activated carbon), Claims 34 and 35 add materials in layer form (see fig 1, REDY). Claims 58 and 59 add the functional limitation of restoring the levels of sodium and bicarbonate in the dialysate to the fresh dialysate levels [functional limitation: While features of an apparatus may be recited either structurally or functionally, claims <directed to >an <apparatus must be distinguished from the prior art in terms of structure rather than function. >In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); <In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).]

It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of REDY in the teaching of Polak (587) as the "zirconium phosphate or its progeny" for purifying the spent dialysate as taught by Polak (col 5 line 60-col 6 line 56).

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Re claims 24 and 25, claim 24 has ratio of ZrO/sodium zirconium carbonate as 1:1 and claim 25 has them blended together. REDY teaches ZrO for removal of phosphate and heavy metals (fig 8 of spec), sodium zirconium carbonate is for the removal of phosphates (Polak). It would be obvious to one of ordinary skill in the art at the time of invention that these two would be put together, since they are for similar functions and one would blend them together, since Polak does not teach any specific the structure of the carbonate in the cartridge. Determining the ratio of the two would be only an optimization [In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).].

3. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of Potts (US 5,234,603).

Polak teaches all the limitations of claim 1. Claims 26-28 adds the further limitations of basic zirconium carbonate, its composition, and purity, respectively, which Polak does not teach. Potts teach the basic zirconium carbonate (pH 9-14) for removal of heavy metals, transition metals and organic matter from wastewater (col 3 lines 55-61, col 4 lines 19-43). It would be obvious to one of ordinary skill in the art at the time of invention to have the teaching of Potts in the teaching of Polak for the removal of heavy metal and transition metal ions from the dialysate as taught by Potts.

4. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of applicant's admitted prior art (REDY) and Potts (US 5,234,603).

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Polak teaches all the limitations of claim 1. Claims 26-28 adds the further limitations of basic zirconium carbonate, its composition, and purity, respectively, which Polak does not teach. REDY teaches Zro in the cartridge for purifying spent dialysate (see specification pages 5-8). Potts teach the basic zirconium carbonate (pH 9-14) for removal of heavy metals, transition metals and organic matter from wastewater (col 3 lines 55-61, col 4 lines 19-43), and that zirconium carbonate would hydrolyze to form the polymeric oxide chain (see structure at lin 35, col 4 of Potts). It would be obvious to one of ordinary skill in the art at the time of invention to have the teaching of REDY and Potts in the teaching of Polak as the "zirconium phosphate or its progeny" for purifying the spent dialysate as taught by Polak (col 5 line 60-col 6 line 56).

5. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of applicant's own admitted prior art (REDY) as applied to claim 16 above, and further in view of Marantz et al (US 3,669,880).

Claims 17 and 18 add structural components like filter pads and diffuser. REDY teaches a filter pad (fig 1), but not the diffuser for flow distribution. Marantz teaches a flow distributor and filter pads (see figures 2,3). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Marantz in the teaching of Polak in view of REDY for the flow distribution and for preventing the breaking up and inter-mixing of particles in layers as taught by Marantz (col 2 lines 10-30).

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of applicant's own admitted prior art (REDY) as applied to claim 3 above, and further in view of Tawil et al (US 4,025,608).

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Polak (587) in view of applicant's own admitted prior art (REDY) teaches all the limitations of claim 3. Claim adds the further limitation of particle size to 30-40 microns for the ZRP particles, which Polak in view of REDY does not teach. Tawil teaches the particle size of ZRP (col 2 lines 54-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Tawil in the teaching of Polak in view of REDY for the particle size of ZrO for good flow distribution as taught by Tawil.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner
July 9, 2003


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